

Food and Drug Administration, HHS

§ 520.905b

(*Oxyuris equi*), and ascarids (*Parascaris equorum*) in horses.

(iii) *Limitations*. Administer by dose syringe or suitable plastic syringe. Do not use in horses intended for human consumption.

(2) *Cattle including dairy cows of breeding age*—(i) *Amount*. Administer orally 5 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

(ii) *Indications for use*. For the removal and control of lungworm (*Dictyocaulus viviparus*); stomach worm (adults)—brown stomach worm (*Ostertagia ostertagi*); stomach worms (adults and 4th-stage larvae)—barberpole worm (*Haemonchus contortus* and *H. placei*) and small stomach worm (*Trichostrongylus axei*); intestinal worms (adults and 4th-stage larvae)—hookworm (*Bunostomum phlebotomum*), threadnecked intestinal worm (*Nematodirus helvetianus*), small intestinal worm (*Cooperia punctata* and *C. oncophora*), bankrupt worm (*Trichostrongylus colubriformis*), and nodular worm (*Oesophagostomum radiatum*).

(iii) *Limitations*. Cattle must not be slaughtered within 8 days following last treatment. A withdrawal period has not been established for this product in prurminating calves. Do not use in calves to be processed for veal.

(3) *Beef cattle*—(i) *Amount*. Administer orally 10 mg/kg of body weight (2.3 mg/lb). Retreatment may be needed after 4 to 6 weeks.

(ii) *Indications for use*. For the removal and control of stomach worm (4th stage inhibited larvae/type II ostertagiasis), *Ostertagia ostertagi*, and tapeworm, *Moniezia benedeni*.

(iii) *Limitations*. Cattle must not be slaughtered within 8 days following last treatment. A withdrawal period has not been established for this product in prurminating calves. Do not use in calves to be processed for veal. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

(4) *Goats*—(i) *Amount*. Administer orally 5 mg/kg of body weight (2.3 mg/lb).

(ii) *Indications for use*. For the removal and control of stomach worms

(adults) *Haemonchus contortus* and *Teladorsagia circumcincta*.

(iii) *Limitations*. Retreatment may be needed after 4 to 6 weeks. Goats must not be slaughtered for food within 6 days following last treatment. Do not use in lactating goats.

[42 FR 59069, Nov. 15, 1977; 43 FR 12311, Mar. 24, 1978. Redesignated at 44 FR 1375, Jan. 5, 1979, and amended at 46 FR 29464, June 2, 1981; 47 FR 15327, Apr. 9, 1982; 48 FR 42809, Sept. 20, 1983; 49 FR 1983, Jan. 17, 1984; 53 FR 40058, Oct. 13, 1988; 59 FR 26943, May 25, 1994; 61 FR 29478, June 11, 1996; 63 FR 63983, Nov. 18, 1998; 66 FR 47960, Sept. 17, 2001; 68 FR 26205, May 15, 2003; 74 FR 17770, Apr. 17, 2009; 74 FR 61516, Nov. 25, 2009; 76 FR 17336, Mar. 29, 2011]

§ 520.905b Fenbendazole granules.

(a) *Specifications*. Each gram of granules contains 222 milligrams (mg) fenbendazole.

(b) *Sponsor*. See No. 000061 in § 510.600(c) of this chapter.

(c) *Special considerations*. See § 500.25 of this chapter.

(d) *Conditions of use*—(1) *Horses*—(i) *Amount*. 5 mg/kilogram (kg) for large strongyles, small strongyles, and pinworms; 10 mg/kg for ascarids.

(ii) *Indications for use*. For the control of infections of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*).

(iii) *Limitations*. Sprinkle the appropriate amount of drug on a small amount of the usual grain ration. Prepare for each horse individually. Withholding feed or water is not necessary. Retreat in 6 to 8 weeks if required. Do not use in horses intended for food.

(2) *Dogs*—(i) *Amount*. 50 mg/kg daily for 3 consecutive days.

(ii) *Indications for use*. For the treatment and control of ascarids (*Toxocara canis*, *Toxascaris leonina*), hookworms (*Ancylostoma caninum*, *Uncinaria stenocephala*), whipworms (*Trichuris vulpis*), and tapeworms (*Taenia pisiformis*).

(iii) *Limitations*. Mix the appropriate amount of drug with a small amount of the usual food; dry dog food may require slight moistening to facilitate mixing. Medicated food must be fully consumed.

§ 520.905c

21 CFR Ch. I (4–1–13 Edition)

(3) *Zoo and wildlife animals*—(i) *Amount.* 10 mg/kg per day for 3 days.

(ii) *Indications for use.* For control of internal parasites of *Felidae* and *Ursidae* as follows:

(A) Lion (*Panthera leo*) and Tiger (*Panthera tigris*): Ascarid (*Toxocara cati*, *Toxascaris leonina*), Hookworm (*Ancylostoma* spp.).

(B) Cheetah (*Acinonyx jubatus*): Ascarid (*Toxocara cati*, *Toxascaris leonina*).

(C) Puma (*Felis concolor*), Panther (*Panthera* spp.), Leopard (*Panthera pardus*), Jaguar (*Panthera onca*): Ascarid (*Toxocara cati*, *Toxascaris leonina*), Hookworm (*Ancylostoma* spp.), Tapeworm (*Taenia hydatigena*, *T. krabbei*, *T. taeniaeformis*).

(D) Black Bear (*Ursus americanus*): Ascarid (*Baylisascaris transfuga*, *Toxascaris leonina*), Hookworm (*Ancylostoma caninum*), Tapeworm (*Taenia hydatigena*, *T. krabbei*).

(E) Polar Bear (*Ursus maritimus*) and Grizzly Bear (*Ursus horribilis*): Ascarid (*Baylisascaris transfuga*, *Toxascaris leonina*).

(iii) *Limitations.* Top dress or mix with a small portion of food. Must be fully consumed prior to feeding. Federal law restricts this drug to use by or on the order of a licensed veterinarian. Do not use 14 days before or during the hunting season.

[44 FR 1375, Jan. 5, 1979, as amended at 47 FR 15327, Apr. 9, 1982; 48 FR 50528, Nov. 2, 1983; 59 FR 35252, July 11, 1994; 66 FR 47960, Sept. 17, 2001; 67 FR 47450, July 19, 2002; 71 FR 19429, Apr. 14, 2006; 74 FR 61516, Nov. 25, 2009]

§ 520.905c Fenbendazole paste.

(a) *Specifications.* Each gram of paste contains 100 milligrams (mg) fenbendazole (10 percent).

(b) *Sponsor.* See No. 000061 in § 510.600(c) of this chapter.

(c) *Related tolerances.* See § 556.275 of this chapter.

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use*—(1) *Horses*—(i) *Indications for use and amounts*—(A) For control of large strongyles (*Strongylus edentatus*, *S. equinus*, *S. vulgaris*), small strongyles, pinworms (*Oxyuris equi*), and ascarids (*Parascaris equorum*): 2.3 mg per pound (lb) of body weight, or for foals and weanlings (less than 18 months of age), 4.6 mg/lb of body

weight. Retreatment at intervals of 6 to 8 weeks may be required.

(B) For control of arteritis caused by the fourth-stage larvae of *S. vulgaris*: 4.6 mg/lb of body weight daily for 5 days. Treatment should be initiated in the spring and repeated in 6 months.

(C) For treatment of encysted mucosal cyathostome (small strongyle) larvae including early third-stage (hypobiotic), late third-stage, and fourth-stage larvae: 4.6 mg/lb of body weight daily for 5 consecutive days.

(D) Fenbendazole paste 10 percent may be used concomitantly with approved forms of trichlorfon for the indications provided in paragraph (e)(1)(i)(A) of this section and for treating infections of stomach bots as provided in § 520.2520.

(ii) *Limitations.* Do not use in horses intended for human consumption.

(2) *Cattle*—(i) *Amount.* 2.3 mg/lb of body weight. Retreatment may be needed after 4 to 6 weeks.

(ii) *Indications for use.* For the removal and control of lungworms (*Dictyocaulus viviparus*), stomach worms (*Haemonchus contortus*, *Ostertagia ostertagi*, *Trichostrongylus axei*), and intestinal worms (*Bunostomum phlebotomum*, *Nematodirus helvetianus*, *Cooperia punctata*, *C. oncophora*, *Trichostrongylus colubriformis*, and *Oesophagostomum radiatum*).

(iii) *Limitations.* Cattle must not be slaughtered within 8 days following last treatment. A withdrawal period has not been established for this product in preruminating calves. Do not use in calves to be processed for veal.

[72 FR 24185, May 2, 2007, as amended at 74 FR 61516, Nov. 25, 2009; 76 FR 17337, Mar. 29, 2011]

§ 520.905d Fenbendazole powder.

(a) *Specifications.* (1) Each 2-ounce packet contains 2.27 grams (4 percent) of fenbendazole plus other inert ingredients.

(2) Each 4-ounce packet contains 1.7 grams (1.5 percent) of fenbendazole plus other inert ingredients.

(b) *Sponsors.* (1) See No. 000061 in § 510.600(c) of this chapter for use of the 4-percent product.